

PATENT
IDEV:020US

UNITED STATES PATENT APPLICATION
for
METHODS FOR SECURING STRANDS OF WOVEN MEDICAL DEVICES AND
DEVICES FORMED THEREBY
by
Jeffery J. Sheldon

EXPRESS MAIL MAILING LABEL	
NUMBER	EL 794535350 US
DATE OF DEPOSIT	March 5, 2002

BACKGROUND OF THE INVENTION

This application claims priority to U.S. Provisional Patent Application Serial No. 60/273,586, filed March 5, 2001.

1. Field of the Invention

5 The present invention relates to methods useful for securing intersections formed by crossed strands of medical devices, such as woven stents. More particularly, the present invention relates to methods that include the use of securing materials to secure intersections formed by crossed strands of medical devices, and the devices formed thereby.

2. Description of Related Art

10 Medical devices serve a variety of uses in the treatment of various vascular and non-vascular disorders. Stents are one example of such medical devices. A stent is a device that may be placed within an internal body structure, such as a blood vessel, to maintain the patency of the internal body structure. For example, when a blood vessel becomes weak and contracted due, for example, to disease and begins to collapse, a stent may be inserted into the blood vessel, placed at the weak or diseased location, and will serve to prop open the weak or diseased portion of the blood vessel in order to allow blood to continue flowing. Various graft materials may also be coupled to stents to form what some term stent grafts. These stents grafts may be thought of as woven frames that
15 have biocompatible jackets coupled to the frames. When an internal body structure such as a blood vessel becomes weak and expands, thereby creating a conduit with a weak, ballooned-out segment, a stent graft may be placed across the ballooned-out segment in order to restore the proper flow of fluid through the body structure.

20 The types of medical devices just described are often woven out of strands of biocompatible material of some kind, as are certain metals. One such woven medical device, in particular a woven stent, is the subject of U.S. Patent No. 4,655,771 to Wallsten (hereinafter "the Wallsten patent"), which is hereby expressly incorporated herein by reference. A version of the subject of this patent is marketed as the WALLSTENT, which is manufactured and sold by Boston Scientific Corporation. Other

2000-03-25 09:58:58

woven medical devices are disclosed in U.S. Patent Application Ser. No. 09/496,243, filed February 1, 2000 and entitled "Woven Intravascular Devices and Methods For Making the Same and Apparatus for Delivery of the Same" (hereinafter "first patent application") and in U.S. Patent Application Ser. No. 09/495,984, filed February 1, 2000 and entitled "Woven Bifurcated and Trifurcated Stents and Methods For Making the Same" (hereinafter "second patent application"), both of which are hereby expressly incorporated herein by reference. The ends of the strands of woven devices may be left free after the weaving process is complete. If delivered into an internal body structure, such as a blood vessel, in such a condition, the free strand ends may damage the internal body structure.

Different steps have been taken to secure the free strand ends of such woven devices. Some methods that have been used in this regard include securing free strand ends using laser welding, soldering, and brazing. These traditional methods may raise issues about material biocompatibility, and may cause problems such as loss of product structural integrity due to a change in material characteristics during the securing process, and the possible introduction of a foreign body into vessel should a piece of welding or soldering material break free. These problems are not intended to be exhaustive, but rather are among many that tend to impair the effectiveness of previously known methods of securing the free strand ends of certain woven medical devices. Other noteworthy problems may also exist; however, those presented above should be sufficient to demonstrate that previous techniques of securing the free strand ends, also described herein as securing the intersection formed by two or more crossed strands, of certain medical devices have not been altogether satisfactory.

SUMMARY OF THE INVENTION

In one respect, a method of securing an intersection formed from two or more crossed strands, in which the intersection defines at least two sections, is provided. The method includes passing a securing material through at least two of the at least two sections defined by the intersection. The passing includes bending the securing material at a location, thereby defining a securing material segment on each side of the location.

The method also includes joining the two securing material segments to secure the intersection.

In other respects, the joining may include tying the two securing material segments. The securing material may include, for example, thread, nylon, metal, or wire.

5 The securing material may be radio opaque. The method may also include gluing the securing material. The method may include heating the securing material. The method may also include cutting excess securing material. In one embodiment, each strand has a free end that extends away from the intersection; the free end of each strand and the intersection may define a strand segment having a length; and the method may include
10 reducing the length of at least one of the strand segments.

In another respect, another method of securing an intersection formed from two or more crossed strands, in which the intersection defines at least two sections, is provided. The method includes bending a securing material, thereby forming a closed end and a securing material segment on each side of the closed end; passing the closed end through
15 at least one of the at least two sections; passing both securing material segments through at least one of the at least two sections; and passing both securing material segments through the closed end to secure the intersection.

In other respects, the method may also include joining the securing material segments. The joining may include tying the two securing material segments. The
20 securing material may include, for example, thread, nylon, metal, or wire. The securing material may be radio opaque. The method may also include gluing the securing material. The method may include heating the securing material. The method may also include cutting excess securing material. In one embodiment, each strand has a free end that extends away from the intersection; the free end of each strand and the intersection
25 may define a strand segment having a length; and the method may include reducing the length of at least one of the strand segments. The method may further include passing each securing material segment at least twice through at least two of the at least two sections.

In still another respect, a device suitable for implantation into a living being is
30 provided. The device includes a body having at least two strands crossed to form an

intersection. The intersection defines at least two sections. The device also includes a securing material passed through at least two of the at least two sections. The securing material is bent at a location and has a securing material segment on each side of the location. The securing material segments are joined together.

5

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings form part of the present specification and are included to further demonstrate certain aspects of the present methods and devices. The present methods and devices may be better understood by reference to one or more of these drawings in combination with the description of illustrative embodiments presented herein. These drawings illustrate by way of example and not limitation, and they use like references to indicate similar elements. The drawings include:

10

FIG. 1 is a front view of a conventionally woven medical device having free strand ends.

15

FIG. 2 is an enlarged view of the intersection of two strands near their free strand ends.

FIG. 3 illustrates one embodiment of a securing material passing through at least two of the sections defined by the intersection of two or more crossed strands.

FIG. 4 is a side view taken from a slight perspective of the intersection and securing material depicted in **FIG. 3**.

20

FIG. 5 illustrates another embodiment of a securing material passing through at least two of the sections defined by the intersection of two or more crossed strands.

FIG. 6 is a side view taken from a slight perspective of the intersection and securing material depicted in **FIG. 5**.

25

FIG. 7 illustrates one manner of joining the securing material segments depicted in **FIG. 5**.

FIG. 8 illustrates yet another embodiment of a securing material passing through at least two of the sections defined by the intersection of two or more crossed strands.

FIG. 9 illustrates an embodiment of a securing material that is bent to form a closed end and two securing material segments in which both the closed end and the two securing material segments are passing through sections defined by two or more crossed strands.

5 **FIG. 10** is a side view taken from a slight perspective of the intersection and securing material depicted in **FIG. 9**.

FIG. 11 depicts passing the securing material segments depicted in **FIG. 9** through the closed end depicted in **FIG. 9**.

FIG. 12 depicts a knot tied in the securing material segments depicted in **FIG. 11**.

10 **FIG. 13** depicts one of the present devices that includes a medical device having an intersection formed from at least two crossed strands, which intersection is secured with a securing material.

FIG. 14 depicts the securing material segments depicted in **FIG. 11** as passing at least twice through at least two of the sections defined by the intersection shown.

15 **DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS**

As a preliminary matter, it should be noted that as used herein, the terms “comprise” (and any form thereof, such as “comprises” and “comprising”), “have” (and any form thereof, such as “has” and “having”), and “include” (and any form thereof, such as “includes” and “including”) are open-ended transitional terms, meaning that a device, a method, or a step in a method that “comprises,” “has,” or “includes” one or more elements or steps possesses those one or more elements or steps, but is not limited to those one or more elements or steps. Thus, and by way of example, a step of passing that includes bending a securing material at a location is a passing that has, but is not limited to, bending a securing material at a location. That is, the passing step in question possesses the recited step of bending, but does not exclude other steps or elements that are not expressly recited.

20

25

The present disclosure details devices created by and methods of securing intersections formed from two or more crossed strands that are part of vascular or non-vascular products. The present methods enhance the structural integrity of the devices in

question, and may serve to eliminate the possible unwinding or release of unsecured, or free, strand ends. Depending on the securing material used, the present methods may be useful in increasing the radiopacity of the devices as well.

FIG. 1 illustrates a conventional woven stent **10**, such as the WALLSTENT, which includes two ends **14**, strands **18**, free strand ends **12**, and intersection **16** formed from at least two crossed strands **18**. As used herein, a stent or other device that is “woven” may be formed using any weaving method disclosed in the Wallsten patent, the first patent application, or the second patent application. Further, strands need not be weaved from end to end of a device for the same to be “woven” as that term is used herein. Further, to the extent not disclosed in these three, the term “woven” as used herein includes all other weaves known to those of skill in the art that may be useful in forming medical devices. Additionally, as used herein, “two crossed strands” includes both two distinct strands that cross each other, as is the case with the strands disclosed in the Wallsten patent, and two portions of the same strand that cross each other, as may be the case with the strands disclosed in, for example, the first patent application. Further still, as used herein, “strands” include any suitably biocompatible materials, including certain polymers and metals.

FIG. 2 illustrates an enlarged view of an intersection **16** formed by crossed strands **18** having free strand ends **12**. Intersection **16** defines sections **20**, **22**, **24**, and **26**. Thus, intersection **16** may be said to define at least two sections. Moreover, intersection **16** may be said to define two pairs of opposing sections—sections **20** and **24**, and sections **22** and **26**.

FIGS. 3 and **4** illustrate one embodiment of a step that may be used as part of the present methods to create the present devices. Specifically, **FIG. 3** illustrates the same enlarged version of the intersection **16** illustrated in **FIG. 2**. **FIG. 3** further illustrates a securing material **30** that is passing through sections **22** and **26**. Thus, it may be said that **FIG. 3** illustrates securing material **30** passing through at least two (i.e., sections **22** and **26**) of the at least two sections defined by intersection **16** (i.e., sections **20**, **22**, **24**, and **26**). As illustrated in **FIG. 3**, securing material **30** is bent at location **32**, which thereby defines securing material segments **34** and **36** on each side of location **32**. The length of

securing material segments **34** and **36** varies, and the two need not always be equal. Such is the case for all securing material segments disclosed herein. It will be understood to those of skill in the art having the benefit of this disclosure that the view depicted in **FIG. 3** may be characterized as being from the perspective of one looking either out through the lumen of a woven device (e.g., a stent) or into the lumen of the woven device.

FIG. 4 is a side view of the securing material and intersection depicted in **FIG. 3**, the side view being taken from a slight perspective. **FIG. 4** is included to illustrate one embodiment of a securing material (i.e., securing material **30**) passing through at least two sections (i.e., sections **22** and **26**). As used herein, a securing material "passing through" a section breaks the plane formed by the strand portions that at least partially outline the section. As illustrated in **FIG. 4**, securing material **30** passing through section **22** breaks the plane formed by strand portions **44** and **46**, which strand portions at least partially outline section **22**. It will be understood by those skilled in the art having the benefit of this disclosure that rarely, if ever, will a strand portion be perfectly straight. In cases in which both strand portions at least partially outlining a section (e.g., strand portions **44** and **46** at least partially outlining section **22**, and strand portions **42** and **48** at least partially outlining section **26**) are perfectly straight, the plane formed thereby will be flat. In cases in which both strand portions at least partially outlining a section share the same curve, the plane formed thereby will be curved. However, should two strand portions at least partially outlining a section do not share the same curve or are not both straight, those strand portions cannot form a plane. Nevertheless, consistent with the manner in which the phrase "passing through" a section is used herein, a plane may be oriented with respect to the two strand portions in question such that volumes of the areas between the plane and the two strand portions (i.e., the area above the strand portions and below the plane, and the area above the plane and below the strand portions) will cancel each other out.

FIGS. 5 and **6** depict an alternate embodiment of a securing material passing through at least two of the sections defined by an intersection. These figures are comparable in terms of the view depicted to **FIGS. 3** and **4**. Specifically, **FIG. 5** depicts securing material **30** passing through sections **20** and **24**, which are at least two sections

defined by intersection 16. Further, FIG. 6 depicts a side view of the securing material and intersection depicted in FIG. 5, the side view being taken from a slight perspective.

In accordance with the present methods, and in the case of any of the embodiments disclosed herein, after a securing material passes through at least two sections, the securing material segments may be joined in any suitable fashion. For example, the securing material segments of a securing material may be joined by tying the securing material segments together. Any suitable knot may be used in this regard. Such knots include square knots, surgeon's knots, square slip knots, and granny knots, to name but a few. In embodiments in which the intersections formed by two or more crossed strands of a stent or other medical device having a lumen (i.e., a passageway therethrough) are secured, the joining may be such that the joined securing material may be partially or completely oriented outside the flow path, or lumen. Such an arrangement may prove to improve the viability of the device in question. It will be understood, however, by those of skill in the art having the benefit of this disclosure that, in certain circumstances, the joined securing material may also be oriented within the flow path, or lumen, of a given device.

FIG. 7 illustrates one manner of joining securing material segments using tying. This manner may be utilized with any of the embodiments disclosed herein. Depending on the material used for securing material 30 (which materials will be discussed below in greater detail) and/or other steps that may be taken, a traditional knot may not be needed to secure intersection 16. This is true with respect to each of the embodiments of the present methods and devices disclosed herein.

For example, the tied securing material segments 34 and 36 illustrated in FIG. 7 may be tightened, and the material used, such that the friction forces acting between the securing material segments suffice to maintain the crossed nature of strands 18. In another embodiment, a suitably biocompatible adhesive may be placed along portions of securing material segments in order to join them or in order to reinforce those that are joined, such as securing material segments 34 and 36 illustrated in FIG. 7. This may be described as gluing securing material segments together. Like gluing, heating securing material, particularly heating securing material segments, may be used in order to join

securing material segments together, or in order to reinforce securing material segments that are joined. This may be described as heating the securing material. The heating may cause some melting of the securing material. Like gluing and heating, compressing securing material, particularly compressing securing material segments, may be an effective way of joining securing material segments together, or in order to reinforce securing material segments that are joined. As used herein, to "secure an intersection" means to take steps to maintain the crossed nature of two or more crossed strands. In this regard, the precise location along each of the two or more crossed strands at which the strands are crossed need not be maintained in order to "secure an intersection."

FIG. 8 illustrates an alternative embodiment to those illustrated in **FIGS. 3** and **5** of a step that may be used as part of the present methods. Specifically, **FIG. 8** illustrates intersection **16** formed by four crossed strands **18**, each have free strand end **12**. Intersection **16** defines sections **20**, **22**, **24**, and **26**. Further, strand portions **42**, **44**, **46**, and **48** illustrated in **FIG. 4** are also illustrated in **FIG. 8**. Any two adjacent strand portions illustrated in **FIG. 8** (such as **42** and **44**, **44** and **46**, **46** and **48**, and **48** and **42**) may be said to at least partially define planes as described above. Securing material **30** is illustrated in **FIG. 8** as passing through sections **22** and **26**. As illustrated in **FIG. 8**, securing material **30** is bent at location **32**, thereby defining securing material segments **34** and **36** on each side of location **32**. Consistent with the present methods and devices, securing material segments **34** and **36** depicted in **FIG. 8** may be joined to secure intersection **16** in any of the manners disclosed herein. Similarly, joined securing material segments may be reinforced in any of the manners disclosed herein.

As used herein, "securing material" includes any suitably biocompatible material, such as nylon, wire, suture, polymer, thread, and the like. Some radio opaque securing materials that may be used include gold and platinum. These radio opaque securing materials may serve to create a visual marker useful to a surgeon during product placement within a living being.

FIGS. 9 and **10** illustrate another embodiment of a step that may be used as part of the present methods to create the present devices. **FIGS. 9** and **10** are comparable in terms of views depicted to **FIGS. 3** and **4** and **FIGS. 5** and **6**. Moreover, the only

difference between the embodiment of the step illustrated in **FIGS. 9** and **10** and the embodiment of the step illustrated in **FIGS. 3** and **4** concerns the orientation of securing material **30**. Specifically, as depicted in **FIG. 9**, securing material **30** has been bent, thereby forming a closed end **35** and securing material segments **34** and **36** on the sides of closed end **35**. Further, securing material **30** passes through at least two of the sections (i.e., **26** and **22**) formed by the crossed strands **18**. More specifically, closed end **35** is depicted as crossing through at least one (i.e., section **22**) of the at least two sections formed from crossed strands **18**. Additionally, both securing material segments **34** and **36** are depicted as passing through at least one (i.e., section **26**) of the at least two sections formed from crossed strands **18**. As with the embodiment depicted in **FIG. 3**, it will be understood to those of skill in the art having the benefit of this disclosure that the view depicted in **FIG. 9** may be characterized as being from the perspective of one looking either out through the lumen of a woven device (e.g., a stent) or into the lumen of the woven device. **FIG. 10** is a side view of the securing material and intersection depicted in **FIG. 9**, the side view being taken from a slight perspective.

In **FIG. 11**, which depicts an embodiment of another step that may be useful with the present methods in creating the present devices, some of the elements numbers have been omitted for ease of references. **FIG. 11** depicts passing securing material segments **34** and **36** through closed end **35**. This step may be used to securing intersection **16** depicted in **FIG. 11**. Further, closed end **35** may be tightened around securing material segments **34** and **36** to further reinforce the securing intersection. Similarly, any the securing intersection may be reinforced using any other manner described herein. Additionally, securing material segments **34** and **36** may be tied in a knot **50**, as illustrated in **FIG. 12**, to further reinforce securing intersection **16**.

Turning now to **FIG. 14**, the securing material segments depicted in **FIG. 11** are shown as being further manipulated. Specifically, **FIG. 14** depicts passing securing material segments **34** and **36** through sections **26** and **22** again, such that each securing material segment depicted in **FIG. 14** passes at least twice through two (i.e., **22** and **26**) of the at least two sections formed by intersection **16**.

One of the present devices, which is suitable for implantation into a living being, is depicted in FIG. 13. Specifically, FIG. 13 depicts a body 10 having at least two strands 18 crossed to form an intersection 16, and a securing material 30 having securing material segments 34 and 36 oriented on both sides of a bent location, which securing material segments are passing through at least two (i.e., sections 20 and 24) of the at least two sections defined by intersection 16. Securing material segments 34 and 36 depicted in FIG. 13 are joined together by virtue of passing through closed end 35, which is tightened around the two securing material segments.

As with all the present methods and devices, excess securing material may be present after it is manipulated to securing an intersection. An example of such excess securing material is illustrated in FIG. 7 as excess material 60. This excess securing material may be cut in any suitable fashion. Furthermore, after an intersection is secured, in addition to cutting excess securing material, the length of free strand ends may be reduced. For example, FIG. 12 shows that strands 18 each have a segment extending away from intersection 16. These strand segments have a length L that may be reduced as desired as part of, or after, intersection 16 has been secured.

While the present disclosure may be adaptable to various modifications and alternative forms, specific embodiments have been shown by way of example and described herein. However, it should be understood that the present disclosure is not intended to be limited to the particular forms disclosed. Rather, it is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure as defined by the appended claims.

Moreover, the different aspects of the disclosed devices and methods may be utilized in various combinations and/or independently. Thus the present methods and devices are not limited to only those combinations shown herein, but rather may include other combinations. Those of skill in the art will understand that numerous other modifications may be made to the disclosed methods and devices, but all such similar substitutes and modifications are deemed to be within the scope of the claims.